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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,685	02/25/2002	Martin P. Redmon	0701100e	4621

7590 10/08/2004

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EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,685	REDMON ET AL	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-60* is/are pending in the application.

4a) Of the above claim(s) *46-48,52-55 and 58-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *41-44, 49-51 AND 55-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The response and declaration filed April 6, 2004 have been received and entered into the file.

The rebuttal arguments filed April 6, 2004 have been considered, but are unconvincing.

Claims 41-60 are presented for examination.

Applicant's election with traverse of group I, claims 41-44, 49-50 and 55-56 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that no undue burden would be placed on Examiner. This is not found persuasive because to search distinct inventions, and set forth separate and distinct rejections for all inventions would place an undue burden on Examiner. Examiner will examine groups I and II. The restriction requirement with regard to these two groups is hereby withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 46-48, 52-54 and 58-60 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 46-48, 52-55 and 58-60 reading on non-elected subject matter are hereby withdrawn from consideration.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 41-45, 49-51 and 55-57 are rejected under 35 U.S.C. § 103 as being unpatentable over Villani et al and Aberg et al, in view of Blaug et al, Hartauer et al, Handbook of Pharmaceutical excipients and Remington's Pharmaceutical Sciences all of record.

Villani et al and Aberg et al teach descarboethoxyloratadine ((997) column 10), ((716) column 21) and analgesic compounds ((997) column 7, lines 15-21) as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating inflammation, viewed by the skilled artisan as immuno-suppressive, and differing from those active

ingredients taught in the prior art, not at all. Claims 41-45, 49-51 and 55-57, and the primary references, differ as to:

1) the recitation of lactose, or sugars as reactive to the active ingredient,

2) recitation of a pill free of lactose, or sugars, and

3) recitation of a coating.

Blaug et al, Hartauer et al, and Handbook of Pharmaceutical excipients teach various amine compounds, in high temperature and humidity situations reacting with various sugars, producing a concomitant reduction in active ingredient levels. The skilled artisan possessing these teachings would have been motivated to eliminate lactose and sugars from those medicaments containing amine active ingredients, such as those herein claimed. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-inflammatory agents, analgesic and decongestant active ingredients, excipients and carriers. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Applicants' claims specifically require lactose free, anhydrous and pill formulations, although not a reciting compositions requiring all three limitations. The skilled artisan would have seen anhydrous pill formulations, free of lactose, and the administration of these medicaments as residing in the skilled artisan purview. Additionally, the skilled artisan, possessing the Blaug et al, Hartauer et al, and Handbook of Pharmaceutical excipients teachings regarding various amine compounds propensity to, in high temperature and humidity situations, to react with various sugars,

producing a concomitant reduction in active ingredient levels would have seen as obvious the elimination of sugars concomitantly with maintaining minimal hydration. The skilled artisan possessing these teachings would have been motivated to eliminate lactose and sugars from those medicaments containing amine active ingredients, while maintaining anhydrous conditions, such as those herein claimed.

Claims 41-45, 49-51 and 55-57 require coating the dosage form with an inert coating agent. Remington's Pharmaceutical Sciences teaches pharmaceutical medicament coatings as an old and well known pharmaceutical practice. These methods are employed for manifold uses by the Pharmaceutical practitioner. To employ one, or another conventional coating method residing in the purview of the skilled artisan would have been seen as the selection from among obvious alternatives.

RESPONSE TO ARGUMENTS

Aberg et al teach a composition, example 8, without a reactive excipient. Example 8, and the composition of claim 41 differ not at all. Carriers and excipients are normally employed as simply carriers and excipients, specifically designed to be non-reactive. Thus, in reciting a non-reactive carrier or excipient, Applicants are simply stating a limitation inherently possessed by these substances.

Attention is directed to Villani et al, column 1, lines 65-69, teaching the claimed compounds as solvated and unsolvated. Subsequently Villani et al describe water and a solvent system, thereby teaching the claimed compounds as anhydrous. The skilled artisan possessing a compound for a therapeutic use, possesses this compounds conventional forms, salts, esters, acids, analogs, homologs, positional isomers and

bioisosteres. Absent some unexpected benefit residing in the anhydrous formulation herein claimed, the selection of anhydrous forms would simply be the selection of an obvious alternative.

Applicants place great weight on a distinction between primary and secondary amines; this reliance is not substantiated by the references of record. Attention is directed to Blaug et al, columns 1-2, page 1770, teaching amines generally, not a specific amine species as responsible for degrading lactose carriers. Possessing this teaching, the skilled artisan would be motivated to not employ lactose carriers with amine active ingredients, regardless the amine species present. Attention is directed to Blaug et al, (page 1774, column 2, paragraph 1) teaching browning, or degradation, reactions as flowing from bound water, motivating the skilled artisan to employ anhydrous conditions when making a tablet composition.

Examiner has considered the declaration from Sharon M. Laughlin and found it unconvincing. Examiner was unaware a Doctor of Philosophy degree in Pharmacy was granted anywhere in the United States. Those claims herein presented are directed to a lactose free composition of matter, with the selection of one, or another, carrier or excipients the simple selection from among obvious alternatives: the Examiner cited art did not require lactose in any formulation thereby obviating the instant presented claims. Dr. Laughlin concludes lactose would not react with lactose, and the instant compositions possess unexpected benefits, absent any information, explanation, or data to substantiate these conclusions.

Applicants aver unexpected benefits residing in the claimed subject matter, yet fail to fails to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is not reasonably commensurate in scope with the instant claims. Absent claims commensurate with a showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant carriers and excipients are not employed concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Examiner would favorably consider claims directed to those medicaments providing unexpected therapeutic benefits, as averred herein. Attention is directed to those data residing in the instant specification, teaching degradation with 80% lactose carrier. Examiner cited prior art teaches a maximum of 40.5% lactose in a tablet form.

Additionally, the prior art teaches the instant active ingredient formulated with 17.5% lactose. Absent a comparison with the closest prior art, the proffered showing is unconvincing.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

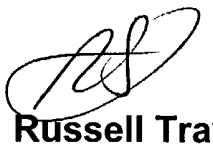
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D.,Ph.D whose telephone number is

571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Russell Travers, J.D, Ph.D.
Primary Examiner
Art Unit 1617